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(54) Title: STENT DELIVERY USING MULTIPLE GUIDEWIRES

(57) Abstract: A method for placing a stent having a side hole into a main vessel such that the side hole is aligned with an ostium of a branch vessel comprises inserting a main vessel guidewire into the main vessel and a branch vessel guidewire into the main vessel until a distal end of the branch vessel guidewire passes into the branch vessel. A catheter system is positioned over the main vessel guidewire and the branch vessel guidewire and comprises a catheter body having a main vessel guidewire lumen and a branch vessel guidewire lumen, and a side member operably coupled to the catheter body. The catheter body further includes a balloon, with the stent being disposed over the balloon. The side member extends into the stent and exits the stent through the side hole. The catheter system is advanced over the guidewires until the catheter body passes beyond the ostium of the branch vessel and the side member extends into the branch vessel. Separation of a set of markers is observed to indicate that the catheter body has passed beyond the ostium and the side member extends into the branch vessel. The balloon is inflated to deploy the stent within the main vessel, with the side hole being aligned with the ostium. The balloon is deflated, and the catheter system is withdrawn from the main vessel and the branch vessel while leaving the main vessel guidewire and the branch vessel guidewire in place.

STENT DELIVERY USING MULTIPLE GUIDEWIRES

BACKGROUND OF THE INVENTION

This invention relates to generally to the field of medical stents. More specifically, the invention relates to techniques for deploying stents into vessels such that a side opening in the stent wall is aligned with an ostium of a branch vessel.

A type of endoprosthesis device, commonly referred to as a stent, may be placed or implanted within a vein, artery or other tubular body organ for treating occlusions, stenoses, or aneurysms of a vessel by reinforcing the wall of the vessel or by expanding the vessel. Stents have been used to treat dissections in blood vessel walls caused by balloon angioplasty of the coronary arteries as well as peripheral arteries and to improve angioplasty results by preventing elastic recoil and remodeling of the vessel wall. Two randomized multicenter trials have shown a lower restenosis rate in stent treated coronary arteries compared with balloon angioplasty alone *(Serruys, PW et al.,* New England Journal of Medicine 331: 489-495 (1994) and *Fischman, DL et al.* New England Journal of Medicine 331:496-501 (1994)), the disclosures of which are herein incorporated by reference. Additionally, regular stents have been used at bifurcation lesions with limited success rates (*Chevalier, B. et al.* American Journal of Cardiology 82:943-949 (1998), *Yamashita T. et al.* Journal of American College of Cardiology 35:1145-1151 (2000) and *Satler S. et al.* Catheterization and Cardiovascular Interventions 50:411-412 (2000). Side branch jailing, fear of plaque shifting and total occlusion and difficulty of the procedure require novel, easier to use, special stents to be developed. Stents have been successfully implanted in the urinary tract, the bile duct, the esophagus and the tracheo-bronchial tree to reinforce those body organs, as well as implanted into the neurovascular, peripheral vascular, coronary, cardiac, and renal systems, among others. The term "stent" as used in this Application is a device that is intraluminally implanted within bodily vessels to reinforce collapsing, dissected, partially occluded, weakened, diseased or abnormally dilated or small segments of a vessel wall.

One of the drawbacks of conventional stents is that they are generally produced in a straight tubular configuration. The use of such stents to treat diseased vessels at or near a bifurcation (branch point) of a vessel may create a risk of compromising the degree of patency of the main vessel and/or its branches, or the

bifurcation point and also limits the ability to insert a branch stent into the side branch if the result of treatment of the main, or main, vessel is suboptimal. Suboptimal results may occur as a result of several mechanisms, such as displacing diseased tissue, plaque shifting, snow plowing, chronic total occlusion, vessel spasm, dissection with or without intimal flaps, thrombosis, and embolism.

As described in related co-pending U.S. Patent Application Nos. 08/744022 filed 11/04/96 (now abandoned); 09/007265 filed 01/14/98; 08/935,383 filed 9/23/97; 60/088301 filed 06/05/98; and 09/663,111, filed 9/15/00; and PCT Patent Application Publication No. WO 99/00835 filed 01/14/98; systems and methods have been developed for deploying a main stent in a main vessel at the intersection of a main vessel and a branch vessel. Further, a branch stent may be positioned within a branch vessel through a side opening in the main stent. The complete disclosure of all these references are herein incorporated by reference.

This invention relates to other novel techniques for deploying stents at such vessel intersections to permit the side opening to be aligned with the ostium of the branch vessel. Some embodiments are particularly directed toward managing the guidewires used to introduce the catheter systems to the region of interest.

SUMMARY OF THE INVENTION

The invention provides systems and methods for deploying a main vessel stent in a main vessel, with a side hole in the main stent being in registry with the ostium of a branch vessel. A variety of catheter designs may be employed to deploy and position the main and branch vessel stents. Such catheters may be used in connection with multiple guidewires that terminate in the main and branch vessels. These guidewires may be used to facilitate introduction of the catheter, any stents, and/or to properly orient the stent within the vessel.

In one particular embodiment, the methods of the invention may utilize a catheter system comprising a catheter body having a main vessel guidewire lumen and a side member that is operably coupled to the catheter body. The side member has a branch vessel guidewire lumen. The catheter body further includes a balloon, and the stent is disposed over the balloon. The side member extends into the stent and exits the stent through the side hole of the stent.

According to one method, a main vessel guidewire is inserted into the main vessel until a distal end of the main vessel guidewire passes beyond the ostium of the branch vessel, and a branch vessel guidewire is inserted into the main vessel until a distal end of the branch vessel guidewire passes into the branch vessel. The catheter system is then advanced over the main and branch vessel guidewires, with the main and branch vessel guidewires passing through the main vessel guidewire and the branch vessel guidewire lumens of the catheter body, respectively.

In the event the guidewires cross, preventing further advancement of the catheter system, the branch vessel guidewire may be withdrawn into the side member to uncross the guidewires. Once uncrossed, the branch vessel guidewire is re-advanced into the branch vessel. At this point, the catheter system may be further advanced over the guidewires until the catheter body passes beyond the ostium of the branch vessel and the side member extends into the branch vessel. The balloon may then be inflated to deploy the stent within the main vessel, with the side hole of the stent being aligned with the ostium. Alternatively, a backup main vessel guidewire may be introduced into the main vessel, and the main vessel guidewire may be withdrawn into the catheter body to uncross the wires.

Optionally, a backup guidewire may be introduced into the branch vessel prior to withdrawing the branch vessel guidewire into the side member. The backup guidewire may then be withdrawn from the branch vessel prior to deploying the stent. Similarly, a backup main vessel guidewire may be introduced into the main vessel prior to withdrawing the main vessel guidewire into the catheter body. The backup main vessel guidewire may then be withdrawn from the main vessel prior to deploying the stent.

In one particular aspect, the catheter body may include at least one radiopaque marker and the side member may also include at least one radiopaque marker. With such a configuration, separation of the markers may be conveniently observed using fluoroscopy toindicate that the catheter body has passed beyond the ostium and the side member has passed into the branch vessel, causing the side hole of the stent to be aligned with the ostium of the branch vessel.

In an alternative method a main vessel guidewire is inserted into the main vessel until a distal end of the main vessel guidewire passes beyond the ostium. A backup branch vessel guidewire is inserted into the main vessel until a distal end of the

backup branch vessel guidewire passes into the branch vessel. The catheter system is then advanced over the main vessel guidewire until reaching the distal end of the guiding catheter, with the backup branch vessel guidewire extending alongside the catheter system. A branch vessel guidewire is inserted through the branch vessel guidewire lumen of the side member of the catheter system until a distal end of the branch vessel guidewire passes into the branch vessel. The catheter system is then advanced over the main vessel guidewire and the branch vessel guidewire until the catheter body extends beyond the ostium and the side member extends into the branch vessel.

Once the stent is in position, the backup branch vessel guidewire is withdrawn from the branch vessel and the balloon may be inflated to deploy the stent within the main vessel, with the side hole being aligned with the ostium. Optionally, a branch vessel stent may also be placed within the branch vessel.

BRIEF DESCIPTION OF THE DRAWINGS

Fig. 1 is a side view of an embodiment of a catheter having a stent that may be deployed within a vessel such that a side hole of the stent is in registry with an ostium of a branch vessel.

Fig. 2 is a cross sectional view of the catheter of Fig. 1, taken along lines 2-2.

Fig. 3 is a more detailed view of a proximal hub of the catheter of Fig. 1.

Fig. 4 illustrates the introduction of a main vessel guidewire and a branch vessel guidewire through a guiding catheter.

Fig. 5 illustrates the introduction of the catheter of Fig. 1 over the guidewires of Fig. 4.

Fig. 6 illustrates the advancement of the catheter of Fig. 1 over the guidewires of Fig. 4 to position the stent at the vessel bifurcation and the separation of side member.

Fig. 7 illustrates inflation of the balloon located at the distal end of the catheter of Fig. 1 to deploy the stent.

Fig. 8 illustrates the stent of Fig. 7 after deployment and with the catheter system removed from the main vessel.

Fig. 9 illustrates the introduction of the catheter of Fig. 1 over the guidewires of Fig. 4, where the guidewires have become crossed.

Fig. 10 illustrates the difficulty in advancing the catheter of Fig. 1 when the side member in Fig. 9 is incorrectly oriented and the guidewires have become crossed.

Fig. 11 illustrates the retraction of the branch vessel guidewire of Fig. 10 into the catheter to untangle the guidewires and to correctly orient the side member.

Fig. 12 illustrates the introduction of a backup branch vessel guidewire through a guiding catheter when the side member in Fig. 10 is incorrectly oriented and the guidewires have become crossed.

Fig. 13 illustrates the retraction of the branch vessel guidewire of Fig. 12 into the catheter and re-advancement back into the branch vessel to untangle the guidewires and to correctly orient the side member while a backup branch vessel guidewire is in the branch vessel.

Fig. 14 illustrates another method for introducing the catheter of Fig. 1 by advancing the catheter over a main vessel guidewire until reaching the distal end of a guiding catheter, while a backup branch vessel guidewire is along side the catheter.

Fig. 15 illustrates the introduction of a branch vessel guidewire into the branch vessel in Fig. 14 by advancing the branch vessel guidewire through a side member of the catheter.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides systems and methods for deploying stents at a vessel bifurcation such that a specifically designed cell to function as a branch aperture referred to as a side hole of the stent throughout this Application, in the stent is in registry with the ostium of the branch vessel. In one aspect, various techniques are provided for managing the guidewires over which the stents and stent delivery catheters are directed. More specifically, the invention provides techniques to help prevent the crossing of guidewires or simply uncross them when introducing catheters used to deploy stents or other devices that require advancement over multiple guidewires, where it is important for the guidewires to be tangle free and parallel with respect to each other. In this way, the catheters may more easily be introduced to the diseased region. More specifically, the distal end of the bifurcation stent delivery catheter and its side member may freely rotate so the side hole of the stent properly faces the ostium of the branch.

Applications of the invention include the cardiac, coronary, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain. Advantages of the invention include, but are not limited to, the use of an improved stent delivery apparatus, which may deliver stents to: 1) completely cover the bifurcation point of bifurcation vessels; 2) be used to treat lesions in one branch of a bifurcation while preserving access to the other branch for future treatment; 3) allow for differential sizing of the stents in a bifurcated stent apparatus even after a main stent is implanted; 4) treat bifurcation lesions in a bifurcated vessel where the branch vessel extends from the side of the main vessel; and 5) be marked with, or at least partly constructed of, material which is imageable by commonly used intraluminal catheterization visualization techniques including but not limited to ultrasound or x-ray.

As described herein, a side hole in the main vessel stent refers to specific cell of the stent, which form a relatively large opening and which is intended to be aligned with the ostium of the branch vessel. Such a side hole is separate from any of the multiple passageways extending through the side of the stent between struts in the stent geometry. Accordingly, the side hole in the stent is a hole, which is understood to be larger than other passages through the stent, except the longitudinal bore of the stent itself. Additionally the side hole of the stent is configured such that a central axis extending perpendicularly through the side hole is generally perpendicular to the longitudinal axis of the stent. In some aspects, this side hole is defined by a band of continuous material, which outlines the perimeter of the side hole. This continuous band of material preferably comprises serpentine patterns over its length so that the area of the side hole expands together with the expansion of the stent. In various aspects, the continuous band comprises protrusions, which project inwardly from a peripheral edge of the side opening and, when expanded, deflect perpendicularly to the longitudinal axis of the stent. Preferably, these protrusions (or expandable portions) are initially aligned within a cylindrical envelope of the tubular body of the stent.

Referring now to Fig. 1, one embodiment of a stent delivery catheter 10 will be described. Catheter 10 may be constructed similar to that described in U.S. Patent Application No. 09/663,111, previously incorporated by reference. Catheter 10 comprises a dual lumen catheter body 12 having a proximal end 14 and a distal end 16. Attached to catheter body 12 is a side member 18 having a proximal end 20 and a distal end 22. As shown in Fig. 1, distal end 22 of side member 18 is detached from distal end

16 of catheter body 12. The length of side member 18 that is detached from catheter body 12 may be in the range from about 2 cm to about 10 cm. Such a configuration is advantageous in that it permits rotation of distal end 16, side member 18 and stent 26 of catheter 10, thereby allowing side hole 28 of stent 26 to correctly orient itself without requiring rotation of the main shaft from the proximal end. In this way, the clinician may easily align the side hole of the main stent with the ostium of the branch vessel without having to rotate the proximal end of catheter 10.

Disposed at distal end 16 is a balloon 24 over which a main vessel stent 26 having a side hole 28 is crimped. Distal end 22 of side member 18 passes between main vessel stent 26 and balloon 24 and exits stent 26 through side hole 28. In this way, distal end 22 may be positioned within a branch vessel stent in a manner similar to that previously described with other embodiments.

As shown in Fig. 2, passing through dual lumen catheter body 12 is a main vessel guidewire lumen 30 and a balloon inflation lumen 32 that is disposed about main vessel guidewire lumen 30. Passing through side member 18 and passing through dual lumen catheter body 12 is a branch vessel guidewire lumen 34. In this way, catheter 10 may be advanced over main and branch vessel guidewires in a manner similar to that previously described with other embodiments. Further, balloon 24 may be inflated using balloon inflation port 40 (see Fig. 3) and balloon inflation lumen 32.

As best shown in Figs. 1 and 3, a proximal hub 36 is coupled to proximal end 14 of catheter 10. Hub 36 further includes a main vessel guidewire port 38, a balloon inflation port 40 and a branch vessel guidewire port 42. Balloon inflation port 40 is in fluid communication with balloon inflation lumen 32 (see Fig. 2) to permit balloon 24 to be inflated and deflated using an inflation device, such as a syringe or an indeflator that is coupled to port 40. Main vessel guidewire port 38 leads to a main vessel guidewire channel 44, and branch vessel guidewire port 42 leads to a branch vessel guidewire channel 46. In this way, a main vessel guidewire 104 may be passed through port 38, through channel 44 and into guidewire lumen 30 (see Fig. 2). In a similar manner, a branch vessel guidewire 106 may be passed through port 42, through channel 46 and into lumen 34 (see Fig. 2).

Channels 44 and 46 are angled relative to each other, preferably at an angle in the range from about 0 to 20 degrees, and more preferably about 10 to about 20 degrees. By configuring channels 44 and 46 in this manner excessive friction may be

avoided when positioning or moving the guidewires within catheter 10. In this way, catheter 10 may more easily be advanced over both guidewires 104 and 106 at the same time. Further, the guidewires are held sufficiently close to permit an operator to simultaneously grasp and hold onto both guidewires with one hand while advancing or withdrawing catheter 10 over the two guidewires with the other hand. In addition, the guidewire ports 38 and 42 are held sufficiently far apart to permit a syringe to be coupled to ports 38 and 42, or to permit separate luer fittings to cover ports 38 and 42.

Referring now to Figs. 4-8, one method for utilizing catheter 10 to deploy stent 26 within a vessel will be described. As shown in Fig. 4, a guiding catheter 100 is initially introduced into the patient through the femoral, radial or any other suitable artery as is known in the art. For convenience of illustration, the diseased sections of main vessel MV and branch vessel BV have been omitted from the figures. With guiding catheter 100 in place, a main vessel guidewire 104 is advanced through guiding catheter 100 and into main vessel MV until guidewire 104 extends past the ostium of branch vessel BV. Typically, main vessel guidewire 104 will be advanced past the diseased region in main vessel MV. A branch vessel guidewire 106 is also routed through guiding catheter 100, through main vessel MV and into branch vessel BV. In some cases, branch vessel BV may also include a diseased region that it to be treated. In that case, branch vessel guidewire 106 will be advanced past the diseased region in branch vessel BV.

With main vessel guidewire 104 and branch vessel guidewire 106 in place, the physician may optionally perform pre-treatment methods to prepare the site for subsequent stent implantation, including techniques such as debulking and "kissing balloon technique" to predialate both vessels to help prevent plaque shift. Such techniques sometimes involve advancing two balloons over guidewires 104 and 106. The balloons are positioned such that when inflated their proximal edges touch or "kiss" each other to prevent plaque shift into one or the other vessel. In other words, main vessel MV and branch vessel BV are exposed to balloon pressures at the same time, and the plaque is compressed without causing it to shift to block the other vessel, an event known in the art as "snowplowing". After the pre-treatment of the arteries, both balloons are withdrawn but main vessel guidewire 104 and branch vessel guidewire 106 are left in place.

Catheter 10 is then loaded onto guidewires 104 and 106, outside of the patient's body. Main vessel guidewire 104 is inserted through main vessel guidewire

lumen 30 (see Fig. 2) and branch vessel guidewire 106 is routed through branch vessel guidewire lumen 34 (see Fig. 2). In this way, main vessel guidewire 104 passes through catheter body 12 and extends into main vessel MV, and branch vessel guidewire 106 extends through side member 18 and out of distal end 22 of side member 18 and extends into branch vessel BV. Hence, as catheter 10 is advanced through guiding catheter 100, guidewires 104 and 106 pass through separate guidewire lumens to prevent wire crossing within the catheter.

As catheter 10 is advanced through the body, fluoroscopically visibly markers on catheter 10 may be observed using standard angiographic imaging, performed at various projections. For example, as shown in Fig. 5, three such markers 108, 110 and 112 are disposed within balloon 24. For convenience of illustration, markers 108, 110 and 112 located within balloon 24 are shown in solid lines. Another marker 114 is disposed on side member 18. Prior to reaching the vessel bifurcation, side member 18 remains close and parallel to the longitudinal axis of stent 26. As such, markers 108, 110, 112, which correspond to proximal, middle and distal portions of stent 26 may be easily observed by angiography. Marker 114 on side member 18 overlaps marker 110 within balloon 24, giving the appearance that there is one marker near the center of stent 26. This indicates that side member 18 has not yet diverged from stent 26 and thus catheter 10 is not yet at the bifurcation point. Obtaining angiographic views of the bifurcation point at various projection angles confirms divergence of the markers and thus side member 18.

As shown in Fig. 6, catheter 10 is then advanced into the area of bifurcation such that side member 18 passes into branch vessel BV and distal end of catheter body 12 passes beyond the vessel bifurcation and further into main vessel MV. This fact may be observed fluoroscopically by noting that marker 114 on side member 18 separates from middle marker 110 within balloon 24. The physician may take angiographic images from various angles to ensure that such marker separation has indeed occurred. Beyond observing the marker separation, advancing catheter 10 too far will result in a feeling of resistance. This is due to side member 18 reaching the crotch of the bifurcation and not having anywhere else to proceed.

When such marker separation has occurred, stent 26 is properly aligned with the ostium of branch vessel BV. Balloon 24 is then inflated and stent 26 is deployed (see Fig. 7). Balloon 24 is then deflated and catheter 10 is carefully withdrawn from the

patient, leaving guidewires 104 and 106 in place (see Fig. 8) for further treatment of main vessel MV and branch vessel BV, should it be necessary. Additionally a branch stent could then be advanced over branch vessel guidewire 106 through side hole 28 of stent 26 into branch vessel BV, without compromising wire position in either main vessel MV or branch vessel BV.

In some cases, crossing of main vessel guidewire 104 and branch vessel guidewire 106 may make it difficult for the physician to advance catheter 10 to the region of bifurcation (see Fig. 9). The wire crossing may prevent catheter 10 from smooth advancement beyond a certain point in main vessel MV and may cause guidewires 104 and 106 to buckle at distal end 102 of guiding catheter 100. Wire crossing may be observed using angiographic imaging. In some situations, because of guidewire crossing, side member 18 may become incorrectly oriented and may extend up and over stent 26, causing rotational tension in catheter 10 (see Fig. 10). If the physician feels that the wires are crossed, one option is to pull back branch vessel guidewire 106 just into side member 18 and thereby release rotational tension in catheter 10, orient side member 18 correctly and eliminate wire crossing (see Fig. 11). As illustrated in Fig. 11, when branch vessel guidewire 106 has been retracted into side member 18, it becomes uncrossed from main vessel guidewire 104. Although not shown, it will be appreciated that main vessel guidewire 104 could be retracted while branch vessel guidewire 106 remains in place. Once the wires have uncrossed and side member 18 has oriented itself correctly, branch vessel guidewire 106 may then be re-advanced back into branch vessel BV for final advancement of catheter 10 as illustrated in Fig. 6.

In some cases, the physician will not wish to leave branch vessel BV unprotected without a guidewire in place. In such cases, the physician may optionally advance a backup branch vessel guidewire 116 into branch vessel BV prior to withdrawing branch vessel guidewire 106 (see Fig. 12). Backup branch vessel guidewire 116 passes through guiding catheter 100, but does not pass through catheter 10. Once backup branch vessel guidewire 116 is in place, branch vessel guidewire 106 may then be withdrawn into side member 18, as illustrated in Fig. 11. Once uncrossed, branch vessel guidewire 106 is then re-advanced back into branch vessel BV (see Fig. 13) for final advancement of catheter 10 as illustrated in Fig. 6. Backup branch vessel guidewire 116 is then withdrawn from branch vessel BV before deploying stent 26.

The use of a backup branch vessel guidewire permits the physician to have a guidewire in branch vessel BV at all times for protection and safety of the arteries in the event of procedural complications.

In some cases, due to size and tortuosity of main vessel MV and branch vessel BV, crossing of main vessel guidewire 104 and branch vessel guidewire 106 may be anticipated in advance of the intervention. In such a case, an alternative technique requiring a backup branch vessel guidewire 116 in addition to main vessel guidewire 104 and branch vessel guidewire 106may be used. Such a technique is illustrated in Figs. 14 and 15. Initially, guiding catheter 100 is introduced in a manner similar to that previously described. Main vessel guidewire 104 is then routed through guiding catheter 100 and down main vessel MV, past the bifurcation point and past the diseased section of main vessel MV. Backup branch vessel guidewire 116 is then inserted through guiding catheter 100, past the bifurcation point and past the diseased section of branch vessel BV. Catheter 10 is then loaded onto main vessel guidewire 104, outside of the patient's body. Main vessel guidewire 104 passes through lumen 30 (see Fig. 2) that extends through catheter body 12. Catheter 10 is advanced through guiding catheter 100 until reaching distal end guiding catheter 102 as illustrated in Fig. 14. Branch vessel guidewire 106 is then inserted into catheter 10 through branch vessel guidewire port 42 (see Fig. 3). Branch vessel guidewire 106 is then advanced to extend through side member 18, out of distal end 22 of side member 18 and is extended into branch vessel BV, leaving catheter 10 still sitting at distal end 102 of guiding catheter 100 as illustrated in Fig. 15. Catheter 10 is then pushed over guidewires 104 and 106 into the area of bifurcation until separation of marker 114 from marker 110 is observed in a manner similar to that previously described. Branch vessel guidewire 106 is withdrawn from branch vessel BV prior to deploying stent 26 in a manner similar to that previously described. Branch guidewire 106 is protected from crossing main vessel guidewire 104 through the length of catheter 10 as it travels in a dedicated branch guidewire lumen 34. The distance over which guidewires 104 and 106 may cross is thus limited to the length between distal end 102 of guiding catheter 100 and the bifurcation point. As previously described, this method minimizes the possibility of wire crossing. In the unlikely event of continued wire crossing, branch vessel guidewire 106 may be pulled back into side member 18 in a manner previously disclosed, ensuring that branch vessel BV is always protected by backup branch vessel guidewire 116. Alternatively, a backup wire may be placed in

main vessel MV, and manipulation of main vessel guidewire 104 may be substituted in the steps previously described.

The invention has now been described in detail for purposes of clarity and understanding. However, it will be appreciated that certain modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A method for placing a stent having a side hole into a main vessel such that the side hold is aligned with an ostium of a branch vessel that extends from the main vessel, the method comprising:

inserting a main vessel guidewire into the main vessel until a distal end of the main vessel until a distal end of the main vessel guidewire passes beyond the ostium of the branch vessel;

inserting a branch vessel guidewire into the main vessel until a distal end of the branch vessel guidewire passes into the branch vessel;

positioning a catheter system over the main vessel guidewire and the branch vessel guidewire, the catheter system comprising a catheter body having a main vessel guidewire lumen and a branch vessel guidewire lumen, and a side member operably coupled to the catheter body, wherein the branch vessel guidewire lumen continues through the side member, wherein the catheter body includes at least one marker and the side member includes at least one marker, wherein the catheter body further includes a balloon with the stent being disposed over the balloon, wherein the side member extends into the stent and exits the stent through the side hole, and wherein the main vessel guidewire extends through the main vessel guidewire lumen and the branch vessel guidewire extends through the branch vessel guidewire lumen;

advancing the catheter system over the guidewires until the catheter body passes beyond the ostium of the branch vessel and the side member extends into the branch vessel;

observing separation of the markers to indicate that the catheter body has passed beyond the ostium and the side member extends into the branch vessel using angiographic imaging;

inflating the balloon to deploy the stent within the main vessel, with the side hole being aligned with the ostium;

deflating the balloon; and

withdrawing the catheter system from the main vessel and the branch vessel while leaving the main vessel guidewire and the branch vessel guidewire in place.

2. A method as in claim 1, wherein if the guidewires are crossed prior to final advancement of the catheter body, withdrawing the branch vessel guidewire into

the side member and re-advancing the branch vessel guidewire back into the branch vessel to uncross the guidewires and to correctly orient the side member.

3. A method as in claim 2, further comprising inserting a backup guidewire into the branch vessel prior to withdrawing the branch vessel guidewire into the side member and withdrawing the backup guidewire from the branch vessel prior to deploying the stent.

4. A method as in claim 1, wherein if the guidewire are crossed prior to final advancement of the catheter body, withdrawing the main vessel guidewire into the catheter body and re-advancing the main vessel guidewire back into the main vessel to uncross the guidewires and to correctly orient the side member.

5. A method as in claim 4, further comprising inserting a backup guidewire into the main vessel prior to withdrawing the main vessel guidewire into the catheter body and withdrawing the backup guidewire from the main vessel prior to deploying the stent.

6. A method as in claim 1, further comprising delivering a branch stent within the branch vessel through the side hole in the main stent.

7. A method for placing a stent having a side hole into a main vessel such that the side hole is aligned with an ostium of a branch vessel that extends from the main vessel, the method comprising:

inserting a main vessel guidewire into the main vessel until a distal end of the main vessel guidewire passes beyond the ostium of the branch vessel;

inserting a backup branch vessel guidewire into the main vessel until a distal end of the backup branch vessel guidewire passes into the branch vessel;

positioning a catheter system over the main vessel guidewire, the catheter system comprising a catheter body having a main vessel guidewire lumen and a branch vessel guidewire lumen, and a side member operably coupled to the catheter body, wherein the branch vessel guidewire lumen continues through the side member, wherein the catheter body includes at least one marker and the side member includes at least one marker, wherein the catheter body further includes a balloon with the stent being disposed

over the balloon, wherein the side member extends into the stent and exits the stent through the side hole, and wherein the main vessel guidewire extends through the main vessel guidewire lumen;

advancing the catheter system over the main vessel guidewire until a distal end of the catheter body is near a distal end of a guiding catheter, and wherein the backup branch guidewire extends alongside the catheter system;

inserting a branch vessel guidewire through the branch vessel guidewire lumen of the catheter system until a distal end of the branch vessel guidewire passes into the branch vessel;

further advancing the catheter system over the main vessel guidewire and the branch vessel guidewire until the catheter body extends beyond the ostium and the side member extends into the branch vessel;

observing separation of the markers to indicate that the catheter body has passed beyond the ostium and the side member extends into the branch vessel using angiographic imaging;

withdrawing the backup branch vessel guidewire from the branch vessel;

inflating the balloon to deploy the stent within the main vessel, with the side hole being aligned with the ostium;

deflating the balloon; and

withdrawing the catheter system from the main vessel and the branch vessel while leaving the main vessel guidewire and the branch vessel guidewire in place.

8. A method as in claim 7, wherein if the guidewires cross prior to final advancement of the catheter body, withdrawing the main vessel guidewire into the catheter body and re-advancing the main vessel guidewire back into the main vessel to uncross the guidewires and to correctly orient the side member.

9. A method as in claim 7, further comprising delivering a branch stent within the branch vessel through the side hole in the main stent.

10. A method as in claim 7, wherein if the guidewires cross prior to final advancement of the catheter body, withdrawing the branch vessel guidewire into the catheter body and re-advancing the branch vessel guidewire back into the main vessel to uncross the guidewires and to correctly orient the side member.

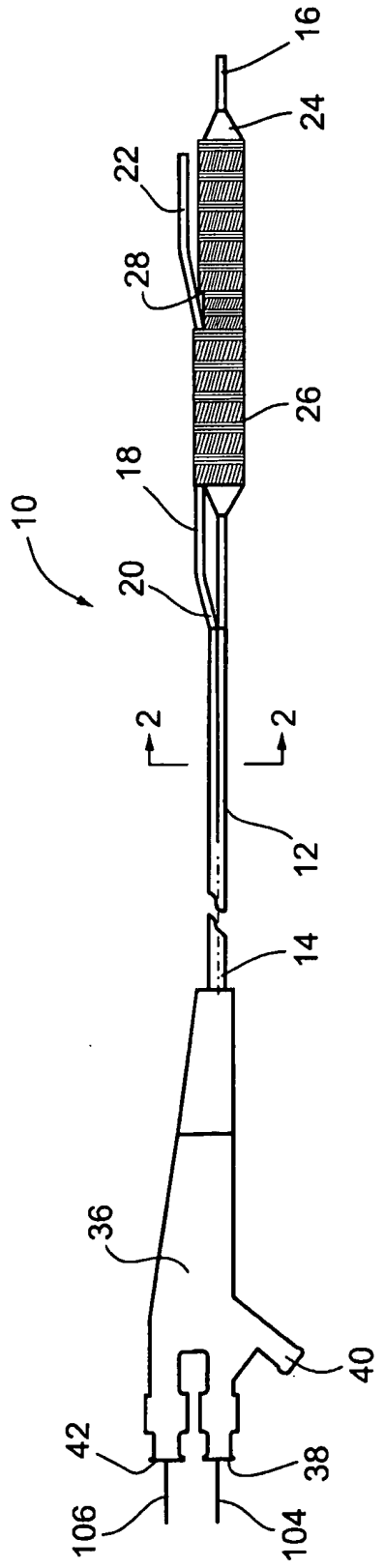

Fig. 1

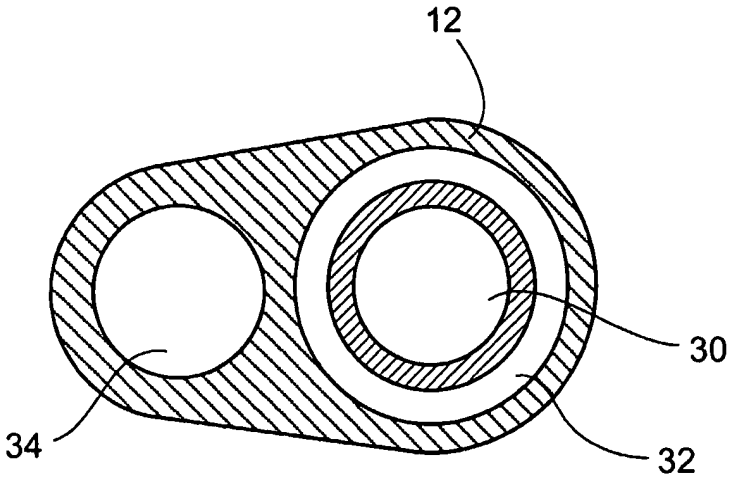

Fig. 2

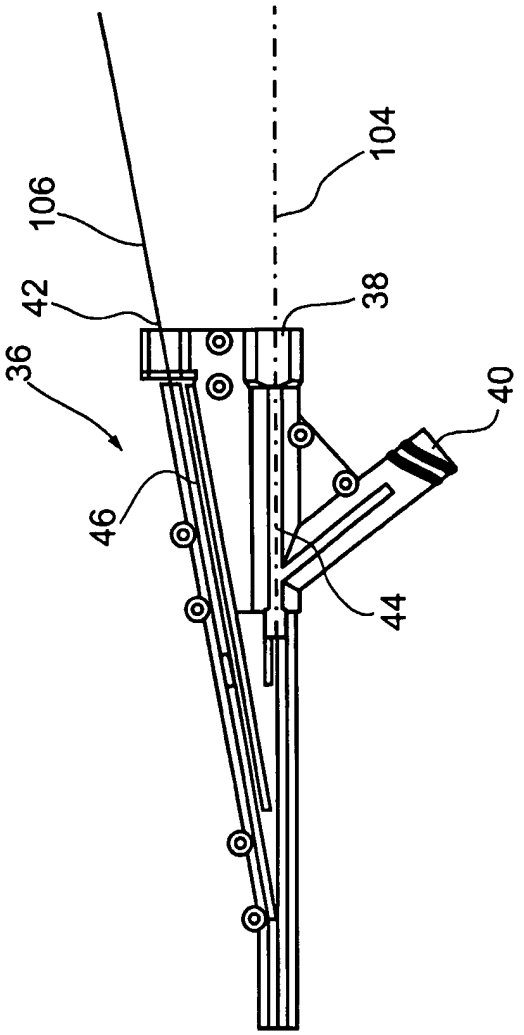

Fig. 3

Fig. 6

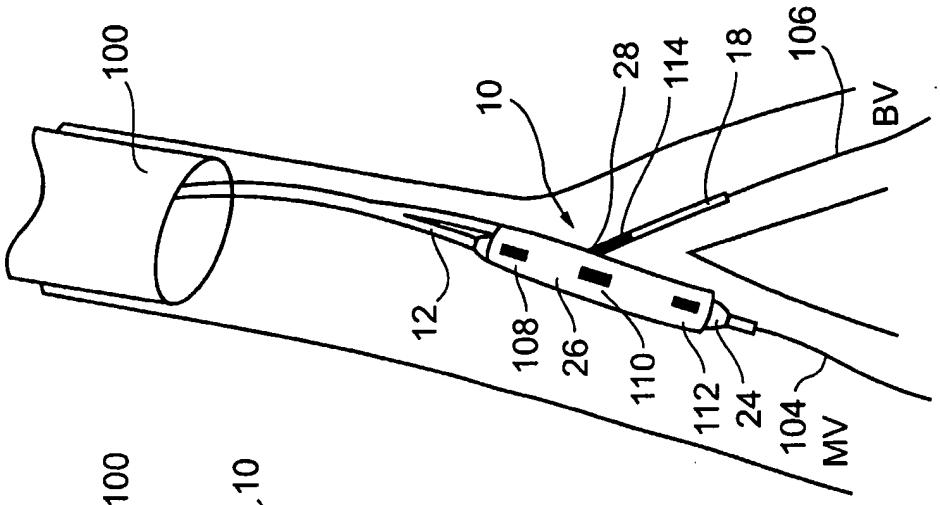

Fig. 5

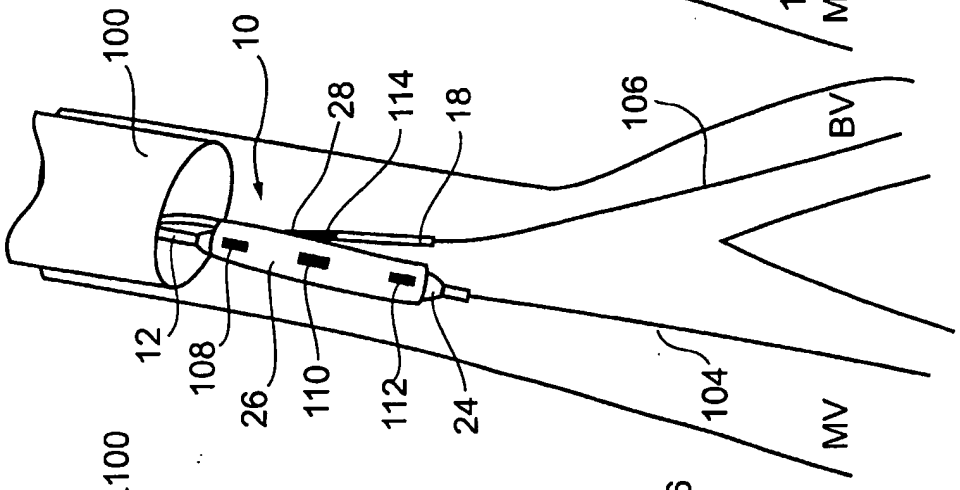

Fig. 4

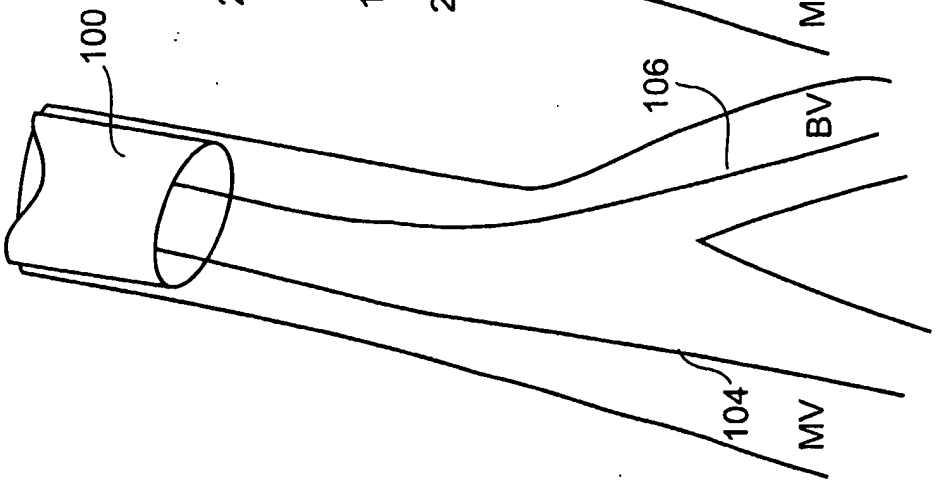

Fig. 9

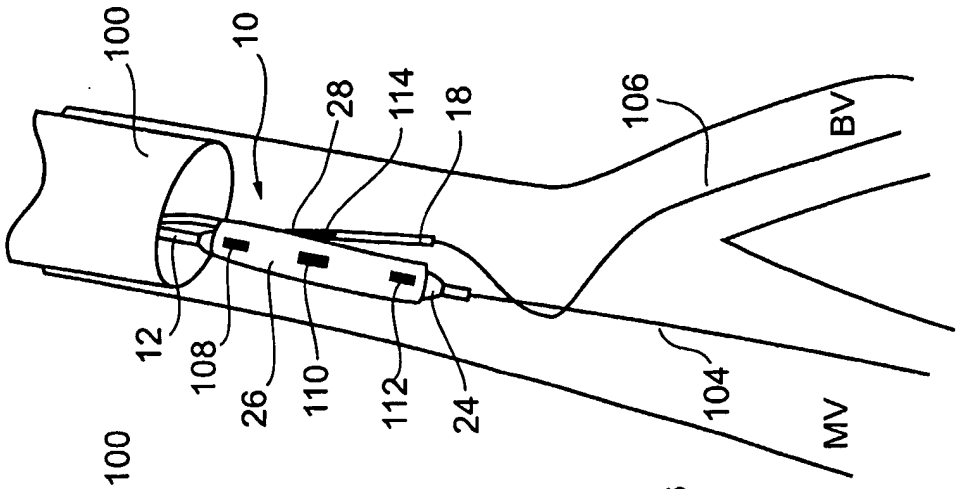

Fig. 8

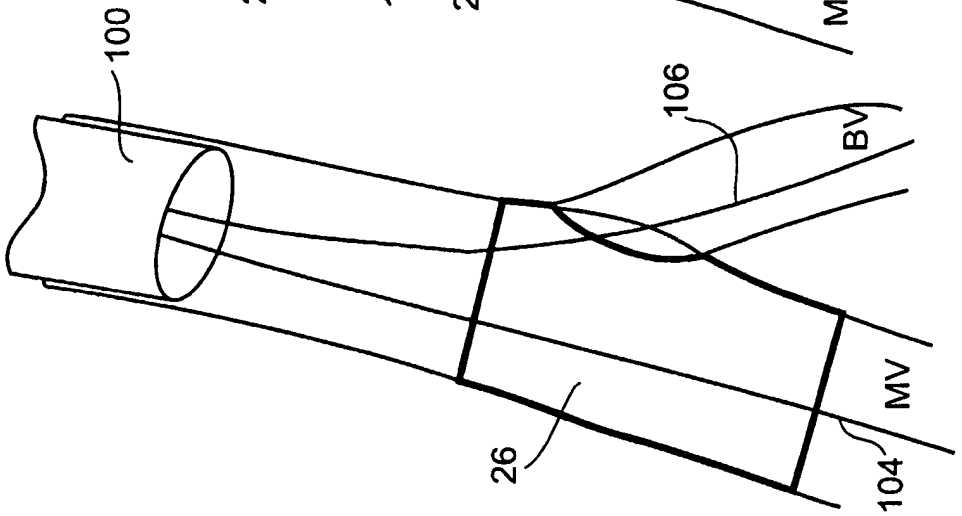

Fig. 7

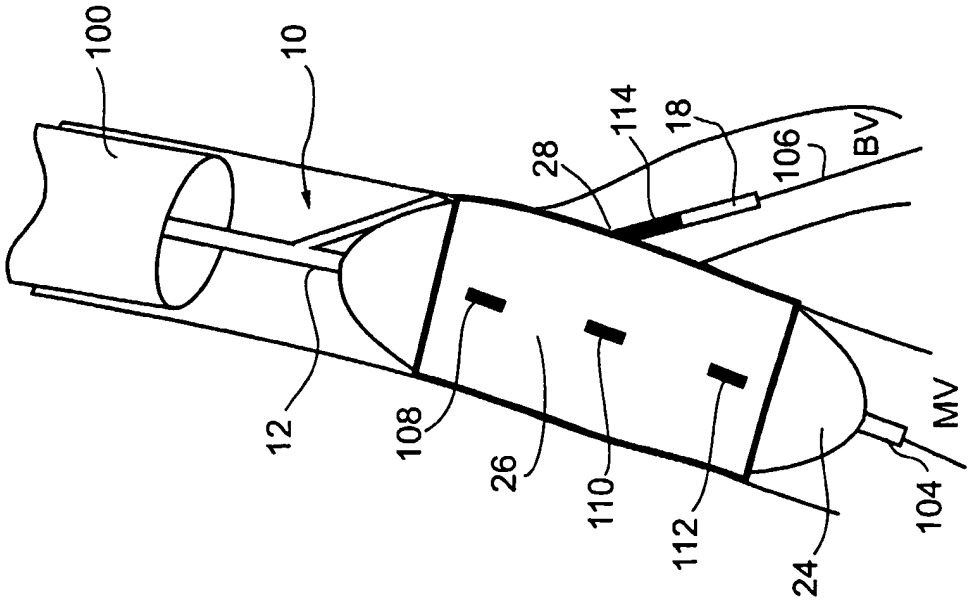

Fig. 12

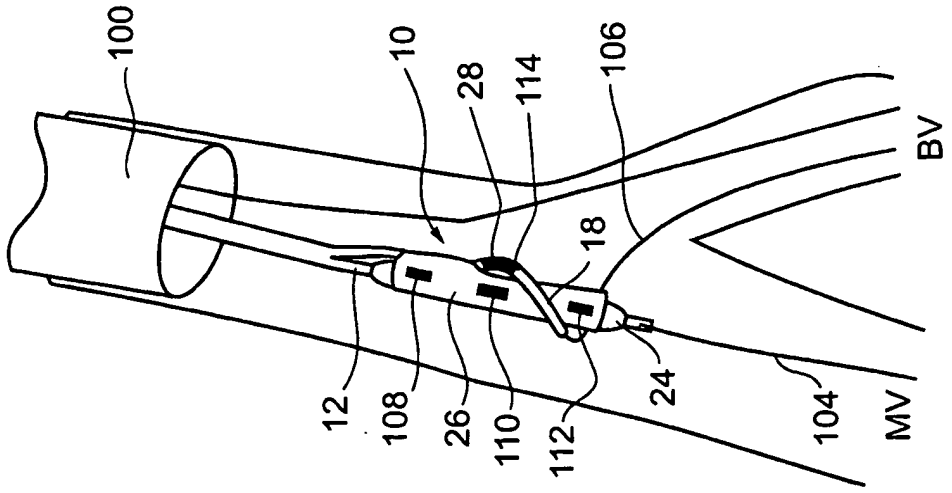

Fig. 11

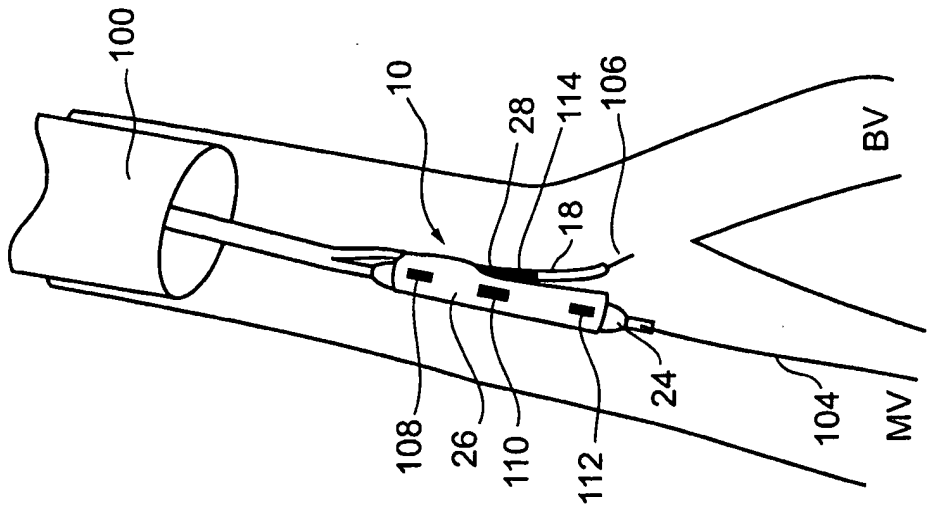

Fig. 10

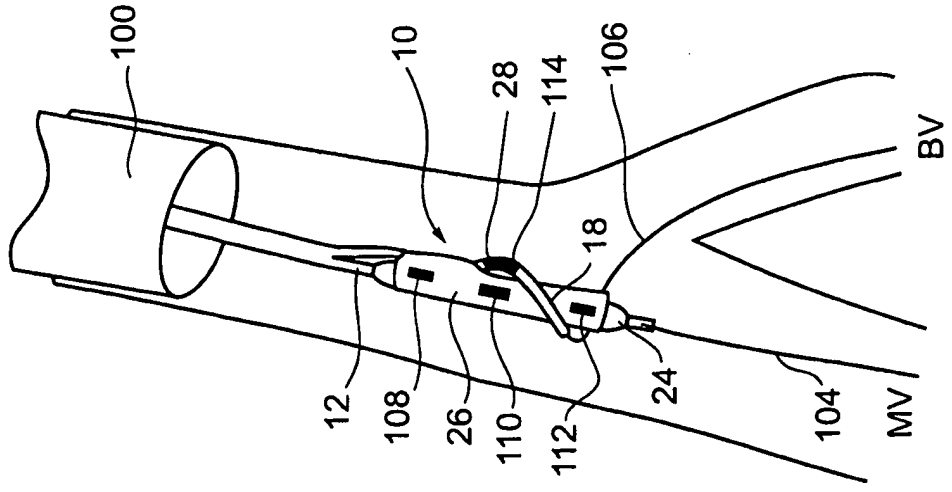

Fig. 15

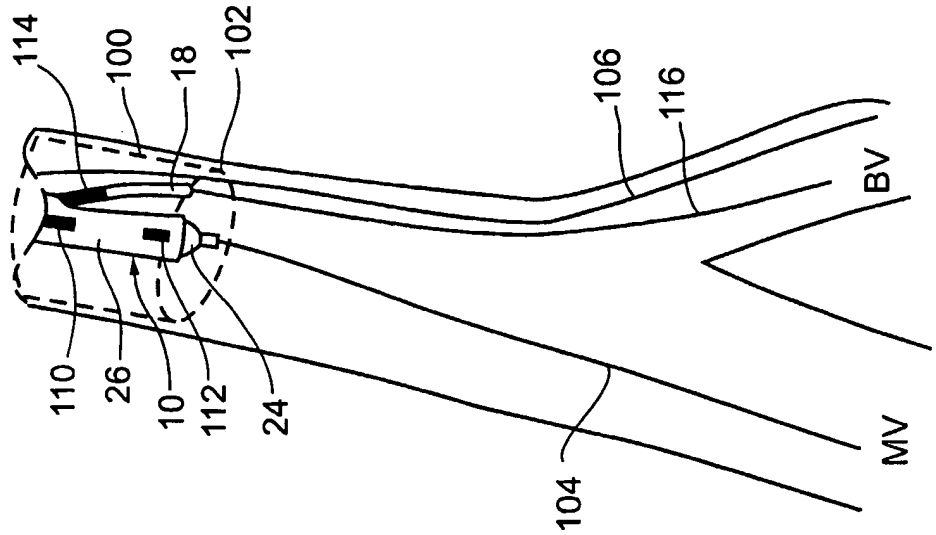

Fig. 14

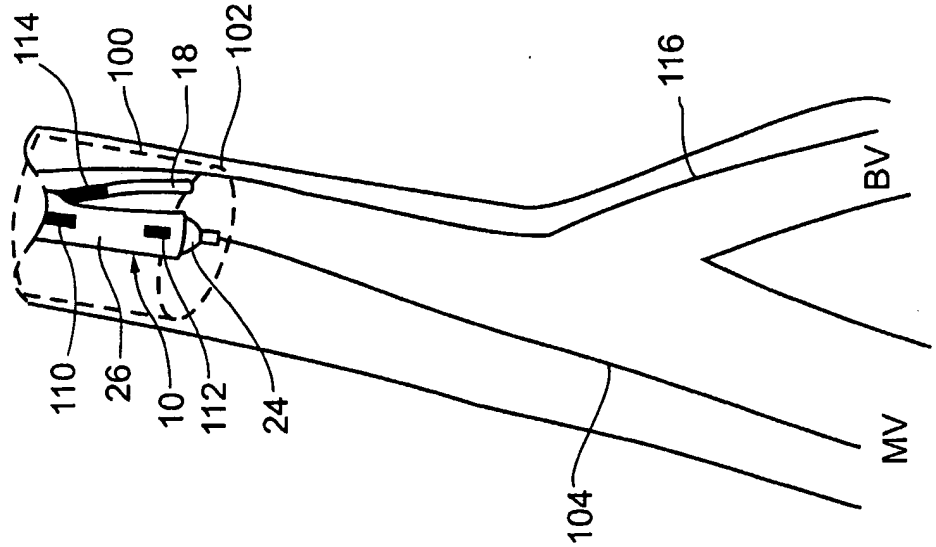

Fig. 13